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EXAMINER

WALLENHORST, MAUREEN

ART UNIT PAPER NUMBER

1743

DATE MAILED: 08/25/2003

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/874,913

Applicant(s)

KELLY ET AL.

Examiner

Maureen M. Wallenhorst

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-32 and 36-40 is/are rejected.
- 7) ☒ Claim(s) 33-35 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3, 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Art Unit: 1743

1. Claims 33-35 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from another multiply dependent claim. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

2. Claims 1-32 and 36-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite and incomplete since it is not clear where the signal generator is located in the device in relation to the sampler. Is the signal generator located on the sampler? Structural cooperation between the sampler and the signal generator is lacking. See this same problem in claim 36.

On lines 3 and 4 of claim 3, the phrase "said sampler washer" lacks antecedent basis since claim 3 depends from claim 1. On line 4 of claim 3, the phrase "said wash solution" lacks antecedent basis.

On line 2 of claim 4, the phrase "said wash solution" lacks antecedent basis. See this same problem on line 1 of claim 5.

On line 2 of claim 6, the phrase "said sample collection pad" lacks antecedent basis since claim 6 depends from claim 1, and claim 1 does not positively recite the sample collection pad.

On line 2 of claim 12, the phrase "said collection pad surface" lacks antecedent basis.

On line 2 of claim 18, the phrase "the sample" lacks antecedent basis.

In claim 19, the recited neutralizing agents "Triton X-100 and Tween 20" are indefinite since these are trademarked materials and subject to change. Materials covered by trademarks are not permitted in claims. Applicants are requested to replace these trademarks with the generic

Art Unit: 1743

names. See this same problem in claim 22 with the material "Coomassie Brilliant Blue dye", and in claim 40.

Claim 23 is indefinite since it is not clear where the reading portion of the device is located in relation to the sampler and the signal generator.

In claim 25, the phrase "said combined sample wash signal generator" lacks antecedent basis. Claim 25 is also indefinite since it is not clear whether the chamber contains the hollow shaft and the absorbent tip of the sampler.

Claim 30 is indefinite since it is not clear where the reagent housing is located in the device in relation to the sampler and signal generator.

On lines 3-4 of claim 36, the phrase "the protein error family" lacks antecedent basis.

Claim 37 is indefinite since it is not clear where the absorbent material is located in the device in relation to the sampler and the signal generator. See this same problem in claim 38 with regards to the wetting agent, and in claim 40 with regards to the wetting solution.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 1743

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-27 are rejected under 35 U.S.C. 102(a) as being anticipated by Carpenter et al (WO 00/09016, submitted in the Information Disclosure Statement filed on Feb. 1, 2002).

Carpenter et al teach of a self-contained sampling/testing device substantially as claimed which comprises a sampler for collecting a target material, a sampler washer comprising a wash solution and a signal generator comprising a dye, which binds to a target material to signal the presence of the target material. The device can include therein an absorbent material, a reagent housing and a wetting/neutralizing solution. The sampler comprises a porous sample collection pad, and the dye and wash solution can be contained in a reagent tray. The dye is a protein binding dye such as Ponceau S, or a frequency shift dye such as Coomassie Brilliant Blue dye. The dye can be dry until contacted by the sampler. The wetting/neutralizing agent can be one of sodium thiosulfate or magnesium chloride. The sampler can comprise a hollow shaft and an absorbent tip. A chamber housing can be combined with the combined sample wash signal generator. This chamber has a breakable shaft, which upon breakage exposes an orifice through which the combined sample wash signal generator flows. The device also can comprise a

Art Unit: 1743

surface, which binds the target material prior to contact of the target material with the dye. See 1-68 and figures 1-8 I Carpenter et al.

6. Claims 1-27 are rejected under 35 U.S.C. 102(e) as being anticipated by Carpenter et al. (US 6,551,834).

Carpenter et al teach of a self-contained sampling/testing device substantially as claimed and as taught by Carpenter et al (WO 00/09016), described in the paragraph above. Therefore, no further explanation is required.

7. Claims 1, 6, 17, 23 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Stone.

Stone teaches of a self-contained sampling/testing device, which comprises a sampler in the form of a swab, and a test reagent impregnated into the swab. The test reagent is a dye that reacts with a sample collected onto the swab to form a detectable color change. The swab is rubbed onto a surface suspected of containing a certain substance (i.e. lead) to collect a sample thereon. If a suspected substance is present on the surface of the swab, a detectable color change occurs. A breakable cartridge 22 in the device contains an activator or wetting solution for wetting the swab prior to sample collection. The dye is also contained in a cartridge 24 in the sampler, which remains dry until a sample test is performed. When the sampler is to be used, the cartridges 22 and 24 are broken, and the activator mixes with the dye and wets the swab. See Figures 1-4 and 14-15, lines 29-50 in column 4, lines 39-48 in column 8 and lines 30-42 in column 10 of Stone.

8. Claims 1,6,13,16,24 and 26-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Numa et al. (submitted in the Information Disclosure Statement filed on October 1, 2001).

Art Unit: 1743

Numa et al teach of a device for detecting proteins in a sample in which a sampling means is contacted with a surface to collect a sample thereon, and the sample is then contacted with a reagent capable of forming a color upon reaction with a protein. In the embodiment depicted in Figure 2, a self-contained device is depicted in which a sampling swab 13 is fixed to the bottom of a cap 7. The swab 13 is contained in a tube 9 having reagents A and B in portions 8 and 12. Reagent A is a dye such as Coomassie Blue for staining protein, while reagent B is a wetting solution. Cap 7 is an upper housing connected to the tube 9, which forms a lower housing. In using the device depicted in Figure 2, the swab is used to wipe a surface suspected of containing a protein and then placed back in the tube 9. The flexible case 11 is destroyed so that reagents A and B are released and contact the swab containing the protein sample. If protein is present on the swab, a color is produced. See Figure 2 and lines 15-45 in column 7 of Numa et al.

9. Claims 1, 17, 20, 23, 29, 36-37 and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Keston (submitted in the Information Disclosure Statement filed on October 1, 2001).

Keston teaches of a protein indicator, which comprises a test paper made by saturating a porous paper with a polychromatic protein detecting solution, and drying in air. The test paper is dipped into a protein-containing liquid, and a color change is observed. The protein detecting solution can be bromophenol blue, a frequency shift dye of the protein error family. The dye signal generator is dry until the test paper (i.e. sampler) is contacted with a sample. See lines 33-65 in column 3 and lines 10-14 in column 4 of Keston.

Art Unit: 1743

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. Claims 29-32 and 36-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over either patent to Carpenter et al (WO 00/09016 or US Patent no. 6,551,834) in view of Keston. For a teaching of Carpenter et al and Keston, see previous paragraphs in this Office action.

The patents to Carpenter et al fail to teach that the signal generator dye can be directly attached to the sample collection absorbent pad, and that the protein detecting dye can be bromophenol blue. Based upon the combination of Carpenter et al and Keston, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to attach the signal generator dye directly to the absorbent sample collection pad of the sampler taught by Carpenter et al since Keston teaches that a dye directly bonded to an absorbent sample collection material allows for the instant reaction between any protein in a sample collected and the dye material since the dye material will instantly contact the protein in the sample collected, thus shortening the reaction time. It also would have been obvious to one of ordinary skill in the art

Art Unit: 1743

to use bromophenol blue as the protein indicator dye in the self-contained sample testing device taught by Carpenter et al since the testing device of Carpenter et al is for the detection of proteins in samples collected from surfaces, and Keston teaches that bromophenol blue is a good protein detection reagent of the protein error family.

13. Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over either patent to Carpenter et al (WO 00/09016 or US Patent no. 6,551,834) in view of Lee (EP 806,666, submitted in the Information Disclosure Statement filed on Feb. 1, 2002).

For a teaching of Carpenter et al, see previous paragraphs in this Office action

Carpenter et al fail to teach that the sampler can comprise an absorbent pad covered by a membrane to which the signal generator dye is attached. Lee teaches of a sample fluid collection test device in the form of a test strip, which comprises an absorbent sample introduction membrane 3 in which a dye can be impregnated for reaction with the sample. See Figure 1 in Lee.

Based upon the combination of Carpenter et al and Lee, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to form the sampler taught by Carpenter et al as an absorbent pad covered by a membrane to which the signal generator dye is attached, similar to the test strip taught by Lee, since Lee teaches that this configuration in a body fluid collection device avoids too much dye-reacted target material from absorbing into the sampler.

Art Unit: 1743

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 703-308-3912. The examiner can normally be reached on Monday-Wednesday from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on (703) 308-4037. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

Maureen M. Wallenhorst
Primary Examiner
Art Unit 1743

mmw

August 18, 2003

Maureen M. Wallenhorst
MAUREEN M. WALLENHORST
PRIMARY EXAMINER
GROUP ~~1800~~ 1700